

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
 United States Patent and Trademark  
 Office  
 Box PCT  
 Washington, D.C.20231  
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 21 August 2000 (21.08.00)	
<b>International application No.</b> PCT/CA99/01151	<b>Applicant's or agent's file reference</b> 1038-996 MIS
<b>International filing date</b> (day/month/year) 02 December 1999 (02.12.99)	<b>Priority date</b> (day/month/year) 04 December 1998 (04.12.98)
<b>Applicant</b> MURDIN, Andrew, D.	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 29 June 2000 (29.06.00)

☐ in a notice effecting later election filed with the International Bureau on:  
 \_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Charlotte ENGER  Telephone No.: (41-22) 338.83.38
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# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 1038-996 MIS		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA99/01151	International filing date (day/month/year) 02/12/1999	Priority date (day/month/year) 04/12/1998	
International Patent Classification (IPC) or national classification and IPC C12N15/87			
Applicant UNIVERSITY OF MANITOBA et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 8 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  29/06/2000	Date of completion of this report  15.02.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Renggli, J  Telephone No. +49 89 2399 7461  

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/01151

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-17 as originally filed

### Claims, No.:

1-40 as originally filed

### Drawings, sheets:

1/5-5/5 as originally filed

### Sequence listing part of the description, pages:

1, filed with the letter of 15.2.2000

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

**INTERNATIONAL PRELIMINARY  
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International application No. PCT/CA99/01151

- ☐ the description,      pages:  
☐ the claims,      Nos.:  
☐ the drawings,      sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:  
**see separate sheet**

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 1-18,29-40 with respect to industrial applicability.

because:

- ☒ the said international application, or the said claims Nos. 1-18,29-40 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.  
☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/01151

## 1. Statement

Novelty (N)	Yes:	Claims	3,7,9,10,15,21,24,31,34
	No:	Claims	1,2,4-6,8,11-14,16-20,22,23,25-30,32-33,35-40
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-40
Industrial applicability (IA)	Yes:	Claims	19-28
	No:	Claims	

## 2. Citations and explanations **see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA99/01151

**ITEM I: Additional observations**

Sequence listing page 1 filed with the letter of 15.02.2000 does not form part of the application (Rule 13<sup>ter</sup>.1(f) PCT).

**ITEM III:**

Claims 1-18 and 29-40 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

For the assessment of the present claims 1-18 and 29-40 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**ITEM V:**

1. Reference is made to the following documents:

D1 WO 98/10789  
D2 Journal of General Microbiology, 1991, Vol. 137, pp. 1557-1564  
D3 WO 98/02546  
D4 WO 98/48026

2. Industrial applicability (Art. 33(4) PCT):

The subject-matter of claims 19-28 is susceptible of industrial application.

**3. Novelty (Art. 33(2) PCT):**

D1 (see the whole document) pertains to an immunogenic composition comprising an outer membrane antigen extract (MAE) of a strain of *Chlamydia*, e.g. *C. trachomatis*. The MAE comprises mainly the major outer membrane protein of the strain of *Chlamydia* (see D1, page 4, lines 27-35; page 10, lines 29-36). The MAE may be injected with ISCOMs preparations, intranasally or intramuscularly; the i.m route and the i.n. route enables the protection of immunized animals (see examples 3 and 4). The composition may also be injected as a booster immunization in combination with an attenuated bacterial vector containing a chlamydial gene-expressing the same chlamydial protein (see D1, page 5, lines 7-25).

D1 is prejudicial to the novelty of claims 1, 2, 4-6, 8, 11-14, 16-20, 22, 23, 25, 26, 29, 30, 32, 33, 35, 36, 39 and 40 (Art. 33(2) PCT).

D2 (see the whole document) is directed to *aroA* strain of *Salmonella typhimurium* (St) carrying a plasmid encoding a *LamB-Chlamydia trachomatis* (Ct) MOMP chimeric protein. The epitopes B1 and B2 from Ct were fused, alone or in combination and with the help of the *lamB* vector pAJC264, with the *E.coli* *LamB* vehicle protein and then introduced into the attenuated *S. typhimurium* SL3261 bacterium (see D2, pages 1558-1559, 1st column; page 1560, table 1). The attenuated St bacteria carrying the recombinant *LamB/MOMP* construct were injected intravenously or orally in C3H/He/Ola mice; the antibody responses against St and Ct was then monitored by ELISA in sera and gut washes of immunized animals (see D2, page 1559, 2nd column; page 1562, table 2; page 1562, 1st and 2nd columns; page 1563).

D2 is prejudicial to the novelty of claims 19, 20, 22, 23, 25-30, 32, 33 and 35-39 of the present application (Art. 33(2) PCT).

**4. Inventive step (Art. 33(3) PCT):**

Claims 3, 7, 15, 21 and 31 differ from the cited prior art in that the strain *Chlamydia pneumoniae* has been selected. The selection of a known and closely related pathogen does not require the exercise of inventive skills. Claims 3, 7, 15, 21 and 31 are therefore not inventive within the meaning of Article 33(3) PCT.

Claim 9 is novel over the closest prior art document D1 because this document does

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA99/01151

not specifically disclose the use of the attenuated bacterium Salmonella. The problem to be solved over D1 by claim 9 can therefore be regarded as the provision of an alternative method for immunizing against Chlamydia (see D1, page 5, lines 7-25). The solution consists in the use of the attenuated bacterium Salmonella. At this stage, it is noted that the use of Salmonella as attenuated vector is widely known in the field of vaccination (see D2 and D4). Consequently, claim 9 is not inventive.

Finally, it should be noted that the use of a CMV promoter is also commonplace in the art (see D3, fig. 7; D4, claims 4 and 7). Claims 10, 24 and 34 are therefore not inventive either.

**ITEM VII:**

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D2 is not mentioned in the description, nor is this document identified therein.

**ITEM VIII:**

1. Claim 19 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem:

"a nucleic acid molecule encoding at least one immunoprotection-inducing Chlamydia protein"

The technical features essential for achieving this result should have been added (cf. PCT Guidelines, Section IV, III-4.4 and III-4.7).

It should also be noted that the description of the present application does disclose a single antigen for achieving this result (i.e. protection of an animal, description of the present application, examples 3 and 4), namely MOMP. It is not apparent where in the description, or in the cited prior art, another antigen of Chlamydia capable of inducing this result has been disclosed. Consequently, the generalization made in claim 19 and consequently in claims 1 and 29 is unallowable, because the skilled person would be unable to extend the particular



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA99/01151

teaching of the description (MOMP) to the whole of the field claimed without the exercise of inventive skills. For that reason, claims 1, 19 and 29 do not meet the requirements of Arts. 5 and 6 PCT, and of the PCT Guidelines, PCT Gazette-Section IV, III-6.2, 6.3 and II-4.9.

2. The subject-matter of claims 1, 19 and 29 is not clear. The Chlamydia protein encoded by the nucleic acid molecule is defined as being "an immunoprotection-inducing Chlamydia protein". It is noted that e.g. the protein MOMP does not appear to be an immunoprotection-inducing protein per se (see description of the present application, pages 2-3), but is merely a protein of Chlamydia trachomatis which enables the generation of a specific immune response and may, under certain circumstances, enable the generation of an immunoprotective response. Consequently, the feature "an immunoprotection-inducing Chlamydia protein" would appear to be superfluous for defining a protein, because this feature relates to the use of the protein; as such this feature introduces unclarity in said claims when used for defining the protein (see the PCT Guidelines, PCT Gazette-Section IV, III-4.8a).
3. The subject-matter of claims 12, 26 and 36 is vague and unclear. It is not clear for the skilled person what the identifying characteristics of pcDNA3/MOMP are (Art. 6 PCT).
4. The attention of the Applicant is drawn to the fact that features between brackets are regarded as totally optional. The features (MOMP) and (ISCOM) are therefore not limiting the scope of claims 2, 6, 13, 14, 30 (PCT Guidelines, PCT Gazette-Section IV; III-4.11)

## PATENT COOPERATION TREATY

RECEIVED

FEB 19 2001

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

STEWART, Michael I.  
Sim & McBurney  
330 University Avenue  
6th Floor  
Toronto, Ontario M5G 1R7  
CANADA

PCT  
SIM & MCBURNEY  
SIM, HUGHES, ASHTON & MCKAY

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 15.02.2001

Applicant's or agent's file reference  
1038-996 MIS

## IMPORTANT NOTIFICATION

International application No.  
PCT/CA99/01151

International filing date (day/month/year)  
02/12/1999

Priority date (day/month/year)  
04/12/1998

Applicant  
UNIVERSITY OF MANITOBA et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

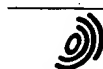
## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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# PCT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>1038-996 MIS</b>	<b>FOR FURTHER ACTION</b> <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, Item 5 below.</small>	
International application No. <b>PCT/CA 99/ 01151</b>	International filing date (day/month/year) <b>02/12/1999</b>	(Earliest) Priority Date (day/month/year) <b>04/12/1998</b>
Applicant <b>UNIVERSITY OF MANITOBA et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

**4. With regard to the title,**

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

**5. With regard to the abstract,**

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

**6. The figure of the drawings to be published with the abstract is Figure No.**

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA 99/01151

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Remark: Although claims 1-18,29-40  
are directed to a method of treatment of the human/animal  
body, the search has been carried out and based on the alleged  
effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/CA 99/01151

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/87 C12N15/31 C12N1/21 A61K31/70 A61K39/118  
 //(C12N1/21,C12R1:42)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HAYES L.J. ET AL.: "Chlamydia trachomatis major outer membrane protein epitopes expressed as fusion with LamB in an attenuated aroA strain of Salmonella typhimurium; their application as potential immunogens." J. GEN. MICROBIOL., vol. 137, 1991, pages 1557-1564, XP000877372 the whole document	1-4, 6-9, 13-22, 27-32, 37-40
Y	WO 98 48026 A (BIOTECHNOLOG FORSCHUNG GMBH ;GUZMAN CARLOS (DE); DARJI AYUB (DE);) 29 October 1998 (1998-10-29) abstract page 9 -page 12 claims 1-9	1-40



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the International filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"G" document member of the same patent family

Date of the actual completion of the International search

7 March 2000

Date of mailing of the International search report

22/03/2000

Name and mailing address of the ISA

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Authorized officer

Galli, I

# INTERNATIONAL SEARCH REPORT

International Application No

CA 99/01151

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application abstract examples 1-6 figure 7 claims 1-33</p>	1-40
A	<p>WO 98 10789 A (UNDERDOWN BRIAN J ;CONNAUGHT LAB (CA); MURDIN ANDREW D (CA)) 19 March 1998 (1998-03-19) cited in the application abstract examples 1-3 claims 1-24</p>	1-18

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

CA 99/01151

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
W0 9848026	A	29-10-1998	AU 5756298 A EP 0977874 A	13-11-1998 09-02-2000
W0 9802546	A	22-01-1998	AU 3431497 A CA 2259595 A EP 0915978 A	09-02-1998 22-01-1998 19-05-1999
W0 9810789	A	19-03-1998	AU 4195897 A EP 0957935 A	02-04-1998 24-11-1999



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b> <b>C12N 15/87, 15/31, 1/21, A61K 31/70, 39/118 // (C12N 1/21, C12R 1:42)</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/34498</b> <b>(43) International Publication Date:</b> 15 June 2000 (15.06.00)
<b>(21) International Application Number:</b> PCT/CA99/01151 <b>(22) International Filing Date:</b> 2 December 1999 (02.12.99) <b>(30) Priority Data:</b> 60/110,855 4 December 1998 (04.12.98) US <b>(71) Applicants (for all designated States except US):</b> UNIVERSITY OF MANITOBA [CA/CA]; 753 McDermot Avenue, Manitoba, Manitoba R3E 0W3 (CA). CONNAUGHT LABORATORIES LIMITED [CA/CA]; 1755 Steeles Avenue, Toronto, Ontario M2R 3T4 (CA). BRUNHAM, Robert, C. [CA/CA]; 108 Brock Street, Winnipeg, Manitoba R3N 0Y4 (CA). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> MURDIN, Andrew, D. [CA/CA]; 146 Rhodes Circle, Newmarket, Ontario L3X 1V2 (CA). <b>(74) Agent:</b> STEWART, Michael, I.; Sim & McBurney, 6th floor, 330 University Avenue, Toronto, Ontario M5G 1R7 (CA).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> With international search report.
<b>(54) Title:</b> TWO-STEP IMMUNIZATION PROCEDURE AGAINST <i>CHLAMYDIA</i> INFECTION  <b>(57) Abstract</b>  A host is immunized against infection by a strain of <i>Chlamydia</i> by initial administration of an attenuated bacteria harbouring a nucleic acid encoding a <i>Chlamydia</i> protein followed by administration of a <i>Chlamydia</i> protein in ISCOMs. This procedure enables a high level of protection to be achieved.		



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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/CA 99/01151

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/87 C12N15/31 C12N1/21 A61K31/70 A61K39/118  
//(C12N1/21,C12R1:42)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HAYES L.J. ET AL.: "Chlamydia trachomatis major outer membrane protein epitopes expressed as fusion with LamB in an attenuated aroA strain of Salmonella typhimurium; their application as potential immunogens." J. GEN. MICROBIOL., vol. 137, 1991, pages 1557-1564, XP000877372 the whole document	1-4, 6-9, 13-22, 27-32, 37-40
Y	WO 98 48026 A (BIOTECHNOLOG FORSCHUNG GMBH ;GUZMAN CARLOS (DE); DARJI AYUB (DE);) 29 October 1998 (1998-10-29) abstract page 9 -page 12 claims 1-9	1-40

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search

7 March 2000

Date of mailing of the international search report

22/03/2000

Name and mailing address of the ISA

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Authorized officer

Galli, I

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 99/01151

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) cited in the application abstract examples 1-6 figure 7 claims 1-33 -----	1-40
A	WO 98 10789 A (UNDERDOWN BRIAN J ;CONNAUGHT LAB (CA); MURDIN ANDREW D (CA)) 19 March 1998 (1998-03-19) cited in the application abstract examples 1-3 claims 1-24 -----	1-18

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA 99/01151

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Remark: Although claims 1-18,29-40  
are directed to a method of treatment of the human/animal  
body, the search has been carried out and based on the alleged  
effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 99/01151

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9848026	A	29-10-1998	AU	5756298 A	13-11-1998
			EP	0977874 A	09-02-2000
WO 9802546	A	22-01-1998	AU	3431497 A	09-02-1998
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			EP	0915978 A	19-05-1999
WO 9810789	A	19-03-1998	AU	4195897 A	02-04-1998
			EP	0957935 A	24-11-1999

# PCT COOPERATION TREATY

**PCT**

## NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

STEWART, Michael, I.  
Sim & McBurney  
6th floor, 330 University Avenue  
Toronto, Ontario M5G 1R7  
CANADA

<b>Date of mailing (day/month/year)</b> 02 October 2000 (02.10.00)	
<b>Applicant's or agent's file reference</b> 1038-996 MIS	<b>IMPORTANT NOTIFICATION</b>
<b>International application No.</b> PCT/CA99/01151	
<b>International filing date (day/month/year)</b> 02 December 1999 (02.12.99)	

1. The following indications appeared on record concerning:

☒ the applicant
 ☐ the inventor
 ☐ the agent
 ☐ the common representative

<b>Name and Address</b> UNIVERSITY OF MANITOBA 753 McDermot Avenue Manitoba, Manitoba R3E 0W3 Canada	<b>State of Nationality</b> CA	<b>State of Residence</b> CA
	<b>Telephone No.</b> (204) 789-3377	
	<b>Facsimile No.</b> (204) 774-1076	
	<b>Teleprinter No.</b>	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☐ the name
 ☒ the address
 ☐ the nationality
 ☐ the residence

<b>Name and Address</b> UNIVERSITY OF MANITOBA 753 McDermot Avenue Winnipeg, Manitoba R3E 0W3 Canada	<b>State of Nationality</b> CA	<b>State of Residence</b> CA
	<b>Telephone No.</b> (204) 789-3377	
	<b>Facsimile No.</b> (204) 774-1076	
	<b>Teleprinter No.</b>	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  Yolaine CUSSAC  Telephone No.: (41-22) 338.83.38
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